

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

# JAN 0 7 2011

## **MEMORANDUM**

SUBJECT: Assessment of Impacts on Flour Mill Operators of a Stay in Sulfuryl Fluoride

**Food Tolerances** 

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Product Review Panel: August 31, 2010

## SUMMARY

The Fluoride Action Network, Environmental Working Group, and Beyond Pesticides have filed objections to the tolerances established for sulfuryl fluoride and sought a "stay" of these tolerances as well. Sulfuryl fluoride, Profume, is a fumigant that was registered for food uses in 2004, to replace methyl bromide, which was being phased out under the Montreal Protocol for Ozone Depleting Substances. Sulfuryl fluoride is registered for cereal grains, such as wheat, corn, and rice, and the mills that process these grains. This assessment focuses on the impact of a stay of food tolerances for sulfuryl fluoride in flour mills in the United States.

Currently, most flour mills are disinfested (completely rid of pests) one to three times per year by means of chemical fumigation. Disinfestation with chemical fumigants is an important part of pest control in mills. Methyl bromide, the primary fumigant used to control stored product pests for decades was phased out under the Montreal Protocol by the end of 2004, except for specific exemptions. Sulfuryl fluoride has been considered the primary chemical alternative to methyl bromide for several years.

BEAD predicts that, if there is a stay in the food tolerances for sulfuryl fluoride, flour mills will switch to one of two alternatives – product removal or heat treatments. One alternative is to move all flour out of the mill to fumigate the facility with sulfuryl fluoride. Mills constructed primarily from wood, which make up about 20-25 percent of the mills in the U.S. may not have the option of using heat treatment. These mills will likely choose the first option, to move all food products out of the mill prior to fumigation of the facility, a method requiring additional expense and days of downtime. This method could result in lower net revenues for flour mill operators, may require several years to transition, and will only be possible if the registrant of sulfuryl fluoride applies for a label change. A second alternative is to use heat treatments to disinfest the mill. Newer mills, i.e., those constructed primarily from concrete, will most likely choose the second option and replace chemical fumigation with heat treatments; this method requires a higher initial investment cost but may cost less than chemical fumigation in the long run. A successful transition to heat treatments could take several years because disinfestation of a large flour mill in both of the scenarios discussed in this analysis will require training and practice before it is fully effective and economically feasible.

If there is an immediate revocation of sulfuryl fluoride tolerances, there is a possibility that contaminated food could enter into the food chain and result in human illness. If contaminated product is identified before entering into the food chain, it would have to be destroyed to comply with FDA regulations. This could cause a disruption in the supply chain and may ultimately result in higher food prices for consumers.

#### BACKGROUND

Sulfuryl fluoride was first registered as a termiticide in 1959 under the trade name Vikane®. The first food uses were registered under the trade name Profume® by Dow Agro Sciences in January 2004. Tolerances for sulfuryl fluoride and fluoride (a metabolite of sulfuryl fluoride) were established for cereal grains, tree nuts and dried fruit. Food uses included structural fumigations of food handling and food processing facilities and direct treatment of commodities including cocoa beans, tree nuts, and dried fruit.

Sulfuryl fluoride as Profume® was developed for food uses to replace the fumigant methyl bromide. Methyl bromide, an ozone depleting substance, is banned under the Clean Air Act (CAA) and under the Montreal Protocol in developed nations by 2005, except for special exemptions. The U.S. has been under intense international pressure to reduce and eliminate methyl bromide uses. Of the 17 developed countries that requested CUEs for 2005, only four countries are still requesting exemptions, of which the U.S. is one. In addition, between the 2005 and 2009 CUEs, the U.S. post-harvest CUEs have been reduced by approximately 50 percent by the parties. In the same time period, the methyl bromide stockpile has been reduced by

approximately 75 percent. The criteria for a critical use exemption are demanding and not easily met. It is improbable that the parties to the Montreal Protocol will approve any additional production of methyl bromide for 2013. It is also unlikely that there will be enough methyl bromide stockpile, pre-2005 inventories, to cover the needs of the post-harvest industry. Because of these restrictions, methyl bromide will not be considered as an alternative to sulfuryl fluoride in this assessment.

#### FLOUR MILLING IN THE UNITED STATES

# Processing of Wheat into Flour

Although each flour mill is unique, all mills have a similar process. A simplified version of the process follows; for further information refer to the North American Millers' Association (NAMA) website.

Wheat arrives by truck, ship, barge, or rail car and is inspected for various qualities before being stored in large grain bins (NAMA, 2010). The wheat kernels are cleaned and scoured to remove the outer husks in several steps.

Next, wheat must be tempered to prepare it for the milling process. The tempering process adds moisture in order to separate various parts of the kernel for milling. Mills have tempering bins that hold these moistened wheat kernels for eight to 24 hours (NAMA, 2010). If tempering bins had to be emptied prior to a fumigation, a day would be needed to empty them. Another day would be needed to restart tempering bins after fumigation.

After tempering, wheat is milled into flour. Milling involves a series of corrugated rollers, sieves, sifters and purifiers, to get smaller and finer particles. The process is repeated until the desired flour is obtained (NAMA, 2010).

# Wheat Flour Market Overview: Production, Value, Consumption, and Capacity

The flour milling industry has underdone significant change over the past few decades. Milling firms and the mills themselves are growing larger and their numbers are decreasing. In 1974, there were 280 wheat flour mills in the U.S. owned by 161 firms (Titus & Dooley, 1996); by 2010, there were 169 mills owned by approximately 70 firms (Grain & Milling, 2010). The overall capacity has also become more concentrated since the 1970s, but that trend has been slightly reversed in recent years. The top four firms in the industry controlled 70 percent of the milling capacity in 1992 compared to 34 percent in 1974 (Wilson, 1995). In 2010, the top four firms controlled 62 percent of the capacity and the top nine firms controlled about 81 percent (Grain & Milling, 2010).

Flour mill structures consist of cement, concrete, stone, slipform concrete, wood, metal and all combinations of these construction materials. In addition, many facilities have been modified several times over the years resulting in many different designs and configurations. It is

<sup>&</sup>lt;sup>1</sup> There are approximately 350 mills in the U.S., but not all produce wheat flour. Some produce bulgar, buckwheat, corn products, durum flour, oats, rice, rye products, soy products, other mixes, or a combination of these products. Some of the 169 mills discussed here produce another product in addition to wheat flour.

estimated that around 20-25 percent of existing flour mills have wood construction. Mills constructed around or after the 1920s were more likely to be constructed from concrete and to be located near a rail line (NAMA, 2010).

Like other food processing establishments, flour mills operate at low profit margins, from one to five percent (North Dakota Auditor, 2009; Kenkel & Holcomb, 2004). These low margins have made it difficult for smaller mills to compete against larger firms that benefit from economies of scale, a condition that has changed the structure of the flour milling industry from one of perfect or monopolistic competition to one of oligopolistic competition over the past several decades (Kim et al., 2001; Wilson, 1995).

# Value of Production

Over the past ten years, an average of 43 percent of the total U.S. wheat supply has been ground for flour. Approximately 400 million hundredweights (cwts) of wheat flour are produced each year in the U.S. (Table 1), nearly all of which is consumed domestically (USDA, 2010). Over the past ten years, production of wheat flour has remained fairly stable ranging between 393,000 and 421,000 cwts per year. Per capita consumption has decreased by about eight percent per capita from 146 to 135 lbs per year.

Table 1. Production of wheat and wheat flour

| Year        | Wheat<br>produced<br>(000s bu) 1 | Price of<br>Wheat<br>(\$/bu) 1 | Wheat used for flour (000s bu) <sup>2</sup> | Wheat flour production (000s cwt) 2 | Price of<br>Flour<br>(\$/cwt) <sup>3</sup> | Price Index<br>of End<br>Products 4 |
|-------------|----------------------------------|--------------------------------|---|-------------------------------------|--|-------------------------------------|
| 2000        | 2,228,160                        | \$2.62                         | 944,868                                     | 421,270                             | \$9.08                                     | 185.9                               |
| 2001        | 1,947,453                        | \$2.78                         | 914,036                                     | 404,521                             | \$9.32                                     | 191.5                               |
| 2002        | 1,605,878                        | \$3.56                         | 889,414                                     | 394,700                             | \$9.05                                     | 197.0                               |
| 2003        | 2,344,415                        | \$3.40                         | 889,188                                     | 396,215                             | \$11.04                                    | 200.2                               |
| 2004        | 2,156,790                        |                                | 876,047                                     | 393,925                             | \$10.63                                    | 204.4                               |
| 2005        | 2,103,325                        | \$3.42                         | 884,101                                     | 394,973                             | \$11.10                                    | 208.2                               |
| 2006        | 1,808,416                        | \$4.26                         | 894,527                                     | 7.403,391                           | \$11.99                                    | 211.2                               |
| 2007        | 2,051,088                        | \$6.48                         | 923,756                                     | 418,836                             | \$13.10                                    | 216.9                               |
| 2008        | 2,499,164 m                      | \$6.78                         | 907,979                                     | 416,283                             | \$23.88                                    | 229.3                               |
| 2009        | 2,216,171                        | \$4.85                         | 896,060                                     | 414,658                             | \$18.39                                    | 255.2                               |
| 2000-09 avg | 2026036                          | \$4.16                         | 901,998                                     | 405,877                             | \$12.76                                    | 210.0                               |
| 2005-09 avg | 2,135,633                        | \$5.16                         | 901,285                                     | 409,628                             | \$15.69                                    | 224.2                               |

Wheat produced and Price of wheat from www.nass.usda.gov/QuickStats/index2.jsp

#### Capacity and Utilization

The combined production capacity of the 169 wheat flour mills in the U.S. was 1.45 million cwts per day in 2009 (Grain & Milling, 2010). Generally, flour mills operate 24 hours per day for 320-340 days per year (CNMA, 2007; Jim Bair, personal communication, August 2010). Mills

<sup>&</sup>lt;sup>2</sup> Wheat ground for flour and Wheat flour production from Wheat Data: Yearbook Tables. Available at www.ers.usda.gov/data/wheat/YBtable28.asp

<sup>&</sup>lt;sup>3</sup> Average of Kansas State and Minneapolis prices from USDA Wheat Data: Yearbook Tables; data in fiscal years; 2000 = 1999-2000; www.ers.usda.gov/data/wheat/WheatYearbook.aspx#Flour

<sup>&</sup>lt;sup>4</sup>U.S. Bureau of Labor Statistics, Cereals and Bakery Products, All Urban Consumers, Current Series, January, Series ID CUSR0000SAF111

are typically closed down from one to three long weekends per year for pest disinfestation (i.e., fumigation) and closed at other times for maintenance. Daily milling capacity of all wheat flour mills was 1.45 million cwts in 2009. Therefore, if all mills operated for an average of 340 days per year (about 6.5 days per week), the annual wheat flour milling capacity in 2009 would have been 492.3 million cwts of flour, 16.8 percent more than what was produced in that year. Table 2 shows national annual capacity for 2009 under different production scenarios. Wilson (1995) also estimated the capacity utilization of the U.S. flour milling industry at approximately 85 percent. The production capacity of 350 days is also considered. The budget used later in this analysis is based on a 350-day operating model; this operating capacity might be possible in a newer mill where less maintenance was needed.

As shown in Table 1, the prices of both wheat flour and end products are increasing. Even if the cost of wheat flour as an input is a relatively small proportion of total costs of production, changes to capacity in the flour milling industry could cause market disruptions that might affect the price of consumer goods.

Table 2. Wheat Flour annual milling capacity under different operating scenarios

|                               | 2009 Total Capacity<br>(000s cwt) † | 2009 Excess Capacity<br>(000s cwt / %) † |
|-------------------------------|-------------------------------------|--|
| Operating 320 days per year   | 463,332                             | 53,704 / 11.6%                           |
| Operating 330 days per year   | 477,811                             | 68,183 / 14.3%                           |
| Operating 340 days per year   | 492,290                             | 82,662 / 16.8%                           |
| Operating 350 days per year * | 506,769                             | 97,141 / 19.2%                           |

<sup>\*</sup> Likely maximum possible operating days per year; shut-downs for disinfestation and minimal maintenance only

Of the 169 flour mills in existence today, about 20-25 percent have wooden construction. However, these are older mills which are likely to be smaller and, therefore, do not account for 20-25 percent of flour production capacity (Jim Bair, personal communication, August 2010).

#### FLOUR MILL INSECT PESTS AND CHEMICAL CONTROL

#### **Key Target Insect Pests of Flour Mills**

The primary pest of flour mills in the U.S. are red flour beetle and confused flour beetle (*Tribolium castaneum* and *Tribolium confusum*, respectively). These small reddish-brown beetles are nearly identical, common, and widespread. They are the most economically important food pests (Mason, 2003; Arbogast, 1991). Historically, the red flour beetle was a warmer climate insect and confused flour beetle occurred in cooler climates, but with the worldwide trade of food and availability of heated buildings both species have become global pests (Mason, 2003; Arbogast, 1991). Stored product pests not only occur in the food but also in all food-associated structures (storage, processing, pantries).

<sup>&</sup>lt;sup>†</sup> Total capacity refers to total annual capacity and is based on 2009 daily milling capacity of 1,447,911 cwts (Grain & Milling, 2010) multiplied by number of operating days. Excess capacity is based on average annual wheat flour production of 409,628,000 cwts from Table 1.

Flour beetles are external feeders and infest a wide variety of plant and animal products, as well as the structures associated with storing and processing these products. In addition to being found commonly on flour, these beetles may be found on grain and cereal products, peas, beans, cocoa beans, nuts, dried fruit, spices, vegetables, spices, dried milk, forest products, hides, and rodent baits (Mason, 2003; Arbogast, 1991). Large populations of beetles can tint flour and other processed foods gray; and their secretions cause foul odors in the food products (Mason, 2003).

Although there are numerous other stored product pests (insects, rodents, birds) that compete for human foodstuffs, for the purpose of this analysis only flour beetles will be considered, since they are the major year-round insect pest in flour mills in the U.S.

#### **FDA Regulations**

The Federal Food, Drug and Cosmetic Act (FFDCA) provides the Food and Drug Administration (FDA) with the authority to safeguard food in the U.S. Under its authority, FDA protects the US food supply by establishing maximum levels of defects, or contaminants, in foods and determines when food becomes adulterated. Food defects include exuviae (shed exoskeleton), body parts and excretia of insects. Some of stored product insects have barbed "hairs" on their bodies and exuviae that are a choking hazard for young children, the elderly, and small pets. In addition, a portion of the population may have allergic reactions to some insects and their body parts.

Although FDA sets the legal limits for defects, American consumers also demand very clean and pest free products. Mills and food processing facilities furnigate to eliminate any pests which could contaminate their products, not only to meet their customers' demands but also to comply with FDA requirements. According to FDA regulations, adulterated products cannot be sold in the U.S. and would likely be destroyed. (Links for FDA are listed in Appendix A).

## Control of Key Target Insect Pests in Flour Mills

#### **Exclusion and Sanitation**

To meet FDA requirements and customer demands, the first line of defense against pests is exclusion, essentially preventing pests from entering the facilities. Exclusion practices include keeping windows and doors closed; keeping seals in good condition; making sure screens are small mesh and in good shape; caulking around windows, doors, and between different building materials; repairing any cracks or crevices in walls and floors; and using insect resistant packaging whenever possible. (Mason, 2003)

Once pests have gained entry into a facility then sanitation is the second line of defense. Cleaning is not usually able to control insects that have gained entry into a flour mill. However, proper sanitation keeps pest populations low and increases effectiveness of control methods (Mason, 2003). Sanitation is divided into two general types: macro-sanitation and micro-sanitation. Macro-sanitation is general cleaning, such as sweeping and vacuuming the floors, wiping walls and "dusting" everything within reach. Micro-sanitation is the thorough cleaning of areas not usually noticed, such as conduits of wires and pipes, electrical outlets, motors within the water fountains, areas within all the operating equipment. This micro-sanitation does not

need special tools, other than toothbrushes, pipe cleaners and cotton swabs, but does take more labor and training (Heaps, 2001; Linda Mason, personal communication, May 2010).

In addition to sanitation, the design of buildings and equipment needs to be considered with regards to easy cleaning and reducing habitat for pests. To minimize harborages, the goal is to reduce dead spaces, cracks, and crevices (Scott, 1991). Buildings and equipment should limit surfaces that can collect organic dusts and that are difficult to reach and clean (Scott, 1991).

Regular inspections of buildings, equipment, and products are critical to managing stored product pests. Checking incoming ingredients to ensure that this is not an entry-way for pests to enter the flour mill is important. It is typical for flour mills to take random samples of wheat to visually inspect for insects. Contaminated grain may be furnigated with phosphine or may be rejected. If product is infested, the flour mill must determine if the pests originated from the warehouse or if the pest is in the equipment.

Monitoring in a flour mill may include traps. Many traps have glue boards to keep insects and their parts within the trap. Some traps use lights to attract night-flying insects to the traps. Some traps may include pheromones, either sex or aggregation, to attract insects. The types and locations of traps target specific species of pests. Night flying moths are more likely to be caught in traps hung from the ceiling; whereas, house fly traps should be around 1.5 m above the floor. Flour beetles tend to crawl so traps along the floor are necessary to monitor their populations. Traps should be monitored frequently and dead insects removed to eliminate an additional food source for pests. Placement of traps within flour mills is variable and depends on the configuration of the mill, flow of product, and pest pressure at the mill. (Mason, 2003)

#### Non-chemical Control

When insect pests are found in a flour mill, there are a couple of non-chemical control methods that may be employed. One such method is temperature manipulation.

For northern locations, and during the winter, some warehouses may be able to use low temperatures. Typically arthropods develop very slowly at low temperatures and cool conditions may kill some insect pests (Scott, 1991; Arthur & Phillips, 2003). If the products can tolerate the cold, then circulating cold air may be an option for some warehouses in deterring infestations (Scott, 1991). Cold is not appropriate for the production areas, because machines generate too much heat, and some equipment, especially electronic, may not be able to tolerate the low temperatures required to kill insects (Arthur & Phillips, 2003).

Heat may also be an option in flour mill pest control. Temperatures of 50-60°C (120-130°F) will kill most stored-product insect pests. Heat must reach the insects and be maintained long enough to kill them (Watters, 1991). Heat leaves no residues but does require the mill, or portions of the mill, to be shut down. Uniform heat distribution requires applicators to take into account the expansion rates of the different materials in a mill and adjust raising and lowering of temperatures to prevent damage to the structure. In addition, weather conditions may also affect the ability of portions of a mill to maintain elevated temperatures.

#### Chemical Control

There are some insecticides, primarily synthetic pyrethroids and insect growth regulators (IGR) that can be used within flour mills. Surface treatments refer to large areas within a mill, such as baseboards and walls. Spot, or crack and crevice, treatments are usually for smaller areas, and may be applied into voids in the structure (hence crack and crevice) (Arthur & Phillips, 2001; Baur, 1991). There are also a few insecticides, aerosols, which are labeled to treat spaces within mills and warehouses (Arthur & Phillips, 2003: Jenson et al., 2010a; Jenson et al., 2010b; Toews et al., 2010). These methods leave some residual insecticide to control pests and are an important component of mill pest management. But these methods do not disinfest mills.

Once a flour mill is infested with insects, the only alternative is to fumigate. In the past, methyl bromide was the fumigant of choice. However, since methyl bromide was banned under the Montreal Protocol, many mills have switched over to sulfuryl fluoride to fumigate. Since methyl bromide is a banned substance, it will not be considered further in this assessment as a pest control option.

Like all fumigants, sulfuryl fluoride is temperature sensitive (i.e., more gas is required as temperature decreases). Some research indicates that insect eggs are less susceptible to sulfuryl fluoride (Fields & White, 2002; Schneider et al., 2003). Sulfuryl fluoride is applied by Precision Fumigation<sup>TM</sup>, a program that determines the minimum gas necessary by taking into account the pests, temperature, half-life, volume, and desired level of control (Profume label).

Another fumigant that might be used in some areas, such as grain or product bins, is phosphine. Phosphine corrodes silver and copper metals and their alloys; therefore, it is unsuitable for production areas of a flour mill, which contain many electronic and electrical materials (Phostoxin label). Less phosphine gas is needed compared to sulfuryl fluoride, but the exposure time is longer. Phosphine has other characteristics that limit its use in a flour mill; for example, it may spontaneously ignite (Phostoxin label).

#### **Evaluation of Likely Alternatives to Sulfuryl Fluoride**

If food tolerances for sulfuryl fluoride were "stayed," i.e. cancelled, there would be no viable chemical control options for flour mill disinfestations. Under this scenario, BEAD predicts that there would be two possible options for millers. One possibility is that flour mills would remove all the ingredients and processed food from the mill, tempering bins, and processing equipment, and then fumigate the empty facility with sulfuryl fluoride. A second possibility is that flour millers would disinfest mills with heat. It is important to note that the first option would require the sulfuryl fluoride registrant to seek amendment of the product label to include directions for use that would not lead to residues in food.

The following analysis evaluates the economic impact of switching to one of the two possible alternatives – moving all flour out of the mill to fumigate with sulfuryl fluoride or using heat treatments to disinfest the mill. Mills constructed primarily from wood, which make up about 20-25 percent of the mills in the U.S. will not have the option of using heat treatment. These mills will have to move all food products out of the mill prior to fumigation, a method requiring additional expense and days of downtime. If the option of moving food products out of the mill before treating with sulfuryl fluoride is not available, there will be no practical treatment options

for mills constructed primarily of wood. Under these circumstances, it may not be economically feasible to continue operation of the mill. Newer mills constructed primarily from concrete will most likely replace chemical fumigation with heat treatments; this method requires a higher initial investment cost but maybe be less expensive than fumigation in the long run.

#### ECONOMIC IMPACT OF STAY OF TOLERANCES ON FLOUR MILL OPERATORS

According to the likely alternatives to traditional sulfuryl fluoride fumigation presented in the biology section, this analysis examines the economic impact of two potential alternative scenarios for flour mills. If there is a stay in the food tolerances for sulfuryl fluoride, mill operators may choose to disinfest mills by: (a) removing all food product from the facility prior to sulfuryl fluoride fumigation or (b) conducting a heat treatment. Older wooden mills would be more likely to choose the first option because using high heat for pest disinfestation is more likely to result in warping and/or cracking of the building in wooden structures (Menon et al., 2000; Beckett et al., 2007). It is estimated that approximately 20-25 percent of the flour mills in the U.S. have wood construction that would prohibit pest disinfestation via heat treatment. These mills will have to remove the product from the facility and production lines prior to fumigation with sulfuryl fluoride to prevent food contact. Newer mills constructed of concrete are more likely to switch to structural heat treatments as their primary mode of disinfestation. It is possible that some mill operators will not know which option is the best for their mill before consulting with heat treatment specialists.

This section uses a partial budget analysis to assess the average impact to flour mills under each scenario over a ten year period and discusses the approximate time needed for transition to one of the alternatives. Transition to either alternative scenario will require initial consultation, planning, and trials to perfect the treatment before they are as effective as current practice.

## The Flour Mill Budget

To conduct the partial budget analyses, a sample flour mill budget prepared by Kenkel and Holcomb (2004) for the Agricultural Marketing Resource Center was used (See Table 3). The capacity of the sample mill is 7,000 hundredweights (cwts) flour per day. The budget assumes that the mill operates 350 days per year and has an annual capacity is 2.45 million cwt of flour. BEAD modified the budget to include a line item for fumigations with sulfuryl fluoride and assumed that this would fall under manufacturing and sales costs; fumigation or pest control was not mentioned in the sample budget. It was also assumed that the cost was already included in variable costs, so the figures for variable costs and manufacturing and sales costs were not changed from the original budget.

It was assumed that a facility fumigates three times per year at a cost of \$19,211 per fumigation (Adam et al., 2010). The cost of a sulfuryl fluoride fumigation in the Adam et al. (2010) study ranged from \$12,391 to \$26,219. This analysis uses the mid-range estimate that was based on average chemical cost and an average dose (40g/m³). The number of fumigations assumed for the model, three fumigations per year, is an upper bound estimate. Some mills fumigate only once or twice per year and some do not even fumigate every year. Using three fumigations will show the highest potential economic impact of the transition.

The average annual net revenue over a ten year period for the sample mill is around \$3.5 million, making the net revenue per cwt \$1.45 (See Table 1). The first and second five year averages from the budget are included in Table 3 to show that returns can vary greatly depending on input costs and the price of flour.

Generally, BEAD assesses the economic impact of a policy change by comparing the cost of the change to an operation's net revenues (total sales less variable costs) over one or more years. In the case of most agricultural crops where investment decisions (i.e., what to plant) are made each season, the cost of a policy change is compared to the net revenues of a single year. Since a flour mill is a multi-decade investment, it is not appropriate to compare the costs of a change to the net revenues of a single year since the operating costs of a single year would not be likely to form the basis of investment decisions. The available budget has ten years of cost and revenue data available, so the average cost of the change over ten years is compared to average net revenue over ten years. However, the costs of the change are likely to be spread over an even longer time period since a flour mill is a long-term investment.

A few details about the purpose of the budget used for the analysis are important to note. The mill budget prepared by Kenkel and Holcomb is a start-up budget; it examines the feasibility of building a new mill. Therefore, there are interest costs and increases in production over time that would not necessarily be true of an existing mill. BEAD modified the revenues in the budget by holding production constant and only allowing price to increase over time. BEAD also removed the fixed costs, which included the interest payments on loans, property taxes, and administrative costs, from the analysis. BEAD did not consider fixed costs as part of this analysis because these costs can vary greatly depending on the location of a particular operation and other factors. Operating costs are more likely to be similar across flour mill operations.

Omitting fixed costs is, in one sense, a limitation of this analysis because it will result in an underestimate of economic impacts. However, the estimate will be a more accurate representation of the economic impacts to operating costs of flour mills, in general. The age of the budget is another limitation to this analysis. It is over six years old; and production costs could have increased in that time. No modifications were made to the budget to account for these possible changes over time.

Table 3. Summary of Flour Mill Income and Expenses Over Ten Years

|                             | Year 1       |         | Year 10      | First<br>5-yr avg | Second<br>5-yr avg | 10-yr avg *  |
|-----------------------------|--------------|---------|--------------|-------------------|--------------------|--------------|
| Total Shipped (cwt)         | 2,450,000    |         | 2,450,000    | 2,450,000         | 2,450,000          | 2,450,000    |
| Total Revenues/Sales        | \$30,429,232 |         | \$33,280,003 | \$31,043,933      | \$32,627,485       | \$31,835,700 |
| Operating Costs             | \$27,031,601 | • • • • | \$29,564,064 | \$27,577,666      | \$28,984,405       | \$28,281,000 |
| Mfg and Sales Costs         | \$1,469,383  | +       | \$1,607,042  | \$1,499,066       | \$1,575,533        | \$1,537,300  |
| Disinfestation <sup>†</sup> | \$57,633     |         | \$57,633     | \$57,633          | \$57,633           | \$57,600     |
| Cost of Goods Sold          | \$25,562,218 |         | \$27,957,022 | \$26,078,601      | \$27,408,872       | \$26,743,700 |
| Net Revenue                 | \$3,397,631  |         | \$3,715,939  | \$3,466,266       | \$3,643,081        | \$3,554,700  |

Fumigation with sulfuryl fluoride, three times @ \$19,211

Sources: Budget from Kenkel and Holcomb (2004); Cost of SF treatment from Adam et al. (2010); BEAD calculations

<sup>\*</sup> Numbers in the 10-year average column are rounded to nearest hundred for use later in the analysis

## Specifications of the sample flour mill

The size of the flour mill in the budget is assumed to be somewhere between 500,000 and one million cubic feet. It is possible for the daily capacity from the budget (7,000 cwt) to be produced in a 500,000 cubic foot facility, but the analysis will consider the possibility of a larger facility so as not to underestimate the impacts. A one million cubic foot mill may actually be able to produce double the daily capacity from the budget and earn much higher revenue. The cost of sulfuryl fluoride fumigation (\$19,211, according to Adam et al., 2010) is based on a one million cubic foot facility. The cost could be around \$7,000 lower for a 500,000 cubic foot facility because less gas is needed, but the cost of labor for setup and electronic equipment for monitoring may not change. Also, a smaller facility could require more gas if it was old and leaky.

#### Scenario #1: Product Removal

Mills that are constructed primarily from wood might not be treated with heat due to risk of warping and cracking of the structure (Menon et al., 2000; Beckett et al., 2007). In these cases, the use of heat for disinfestation would be either technically infeasible due to the possibility of structural damage or economically infeasible due to the time needed to slowly heat the plant to prevent the structural damage. These mills may opt to remove all food products from their facility in order to keep using sulfuryl fluoride for disinfestation. It is important to note, however, that this scenario would only be possible if the registrant of sulfuryl fluoride were willing to seek an amendment of the product label that would permit this type of use.

## Cost Categories and Estimates

Labor to move product. To move all food product out of a mill in preparation for a structure-only fumigation requires planning to empty the tempering bins and pare down inventories. Directly preceding the fumigation, it would be necessary to move all food product out of the mill and attached warehouses. One estimate of labor needed to perform this task indicated that 10-15 people could remove the product for a mill with a capacity of 8,000 cwts per day in approximately 24 hours; five people could then replace it after the fumigation and get the mill running again in about 12 hours (Ron Galle, personal communication, July 2010). Although this estimate is somewhat imprecise, it will be assumed that an additional 15 persons are needed for 24 hours and five persons are needed for an additional 12 hours – an additional 420 hours of labor. At an average hourly rate of \$16.00, this amounts to \$7,680. Assuming that fumigation occurs three times per year, the total annual cost of additional labor will be \$23,040.

Additional days of downtime. A typical sulfuryl fluoride fumigation can be completed in a matter of three days. To completely empty and restock the facility would require an additional 36 hours of downtime, 24 hours to empty the mill and another 12 hours to refill and restart the tempering bins. To get the most efficacious treatment, millers typically do draw down their flour inventories prior to fumigation. However, they typically do not totally clean out the tempering

<sup>&</sup>lt;sup>2</sup> A personal communication with Ken Schuman (June 2010), Star of the West Mill, indicated that one of their mills with a daily capacity of 8,000 cwts is approximately 500,000 cubic feet.

<sup>&</sup>lt;sup>3</sup> The average hourly earnings of production and non-supervisory employees in the manufacturing sector was \$15.94 in Jan 2004, the year the budget was constructed (U.S. Bureau of Labor Statistics, 2004).

bins. In this case, BEAD accounts for the time required to empty and then refill the tempering bins.

Assuming three fumigations, there is a total of 108 hours or 4.5 days of lost production. The impact of the additional 4.5 days of downtime on annual revenues can be found in one of two ways. One way is to calculate the value of the production that would have occurred during those 4.5 days and subtract it from total revenue. At a production capacity of 7,000 cwts per day, production is reduced by an additional 31,500 cwts. Multiplying 31,500 cwts by the average price of flour from 2000-2009 from Table 1 (\$12.76) equals a reduction in revenues of about \$402,000 or 1.25 percent. Another way to calculate the loss is to assume that the total revenue in the budget is earned over a period of 350 days and proportionately reduce the total to represent 345.5 days. By this method, total revenues are reduced by \$409,300 or 1.29 percent. The latter estimate is used for the analysis.

Initial investment costs. If the food product is to be moved out of the facility before fumigation, there must be a place to store it. There may be additional costs of investing in trailers or rail cars to store product while a facility is being fumigated. While some flour mills own their own fleet of rail cars or trailers, some still choose to sublease the cars. Assuming that rail cars are subleased, the cost of leasing two train cars for product storage will run between \$900-\$1,000 per month (Ken Schuman, personal communication, June 2010). A facility will only need to rent the cars during the months that it fumigates, so the analysis assumes three months of rental costs for two cars (approximately \$6,000). However, the cost may be lower if the facilities can rent the cars for a portion of the month rather than the entire month.

# Economic Impact of Switch to Product Removal Scenario

Table 4 shows the results of the partial budget analysis for Scenario #1. Under the product removal scenario, the total revenues of the sample flour mill are reduced by an average of \$409,300 (1.3%) from the additional days of downtime. Total costs decrease by an average of \$314,800 (1.1%) from an increase in manufacturing costs of \$29,000 (1.9%) from the additional cost of labor and rail cars and a \$343,800 (1.3%) decrease in cost of goods sold. With more days of downtime, production is decreased. Cost of goods sold are the direct inputs into flour production (e.g., grain and other ingredients). If production is reduced, these purchases are not necessary. Overall, net revenue decreases by an average of \$94,500 (2.7%) per year.

Table 4. Summary of Flour Mill Income and Expenses Over Ten Years under Scenario #1: Product Removal

|                              | 10-yr avg:<br>Baseline | 10-yr avg:<br>Scenario #1 | Change      |
|------------------------------|------------------------|---------------------------|-------------|
| Total Shipped (cwt)          | 2,450,000              | 2,418,500                 | -31,500     |
| Total Revenues/Sales         | \$ 31,835,700          | \$ 31,426,400             | -\$ 409,300 |
| Operating Costs              | \$ 28,281,000          | \$ 27,966,200             | -\$ 314,800 |
| Mfg and Sales Costs          | \$ 1,537,300           | \$ 1,566,300              | \$ 29,000   |
| Disinfestation 1             | \$ 57,600              | \$ 57,600                 |             |
| Labor to move product 2      |                        | \$ 23,000                 | \$ 23,000   |
| Rent of trailers/rail cars 3 |                        | \$ 6,000                  | \$ 6,000    |
| Cost of Goods Sold 4         | \$ 26,743,700          | \$ 26,399,900             | -\$ 343,800 |
| Net Revenue                  | \$ 3,996,000           | \$ 3,460,200              | -\$ 94,500  |

<sup>&</sup>lt;sup>1</sup> Fumigation with sulfuryl fluoride, three times @ \$19,211, costs \$57,633; rounded to \$57,600.

# Results based on one disinfestation per year

Some facilities fumigate only once per year and some only once every two or three years. This may be due to the fact that the facility is in a cooler climate or has low pest pressure for some other reason. If facilities underwent fewer fumigations, they would not have as many days of downtime for the product removal scenario, which is the most significant portion of the impact on net revenues. Under the product removal scenario with one fumigation, the total revenues of the flour mill would be reduced by an average of \$136,400 (0.4%) from the additional days of downtime. Total costs decrease by an average of \$104,900 (0.4%) from an increase in manufacturing costs of \$9,700 (0.6%) from the additional cost of labor (\$7,700) and rail cars (\$2,000) and a decrease of \$114,600 (0.4%) in cost of goods sold. Overall, net revenue decreases by an average of \$31,500 (0.9%) per year over the ten year period, and this change in net revenues could be expected to recur every year. Fixed costs are not included due to their high variation across flour mill operations, but the percent change in profits (total revenues minus total costs) would be higher than the percent change in net revenues (total revenues minus operating costs).

# Expected Transition Time for Scenario #1

To transition from chemical fumigation with food contact to fumigation without food contact, a flour mill will need time to plan and practice making the necessary personnel and inventory adjustments. At most, a facility will fumigate three times per year. This only provides a few times per year for management to learn which floors of the mill to empty first, when to begin emptying the mill before the scheduled fumigation, exactly how many people will be needed, when and how to lease the train cars or freight vans for storage, and other details about this method. Also, to minimize the time needed to prepare the mill for fumigation, it would be ideal to have stocks at a minimum before the product removal exercise and fumigation takes place. Therefore, mills pursuing this alternative will have to assess their inventory patterns and, if

<sup>&</sup>lt;sup>2</sup> An additional 420 hours of labor paid at an average hourly rate of \$16.00 equals \$7,680. With three fumigations per year, the total annual cost of additional labor will be \$23,040; rounded to \$23,000.

<sup>&</sup>lt;sup>3</sup> Two train cars are needed for each fumigation; each train car costs \$900-\$1,100 per month to rent. Total cost of train car rental is \$6,000.

<sup>&</sup>lt;sup>4</sup> Cost of goods sold includes grain, transportation, and packing material. If production is lower, these costs will also decrease, so they are reduced by the same proportion as total revenues.

necessary, determine how to adjust delivery patterns so that machines can be emptied and a minimum number of trailers or rail cars rented to store remaining product. The logistics of this operation are not well understood at this time since this is not the current practice in the U.S. flour mill industry. BEAD thinks that it could take several years of practice to refine the product removal scenario to the point where it is not cost prohibitive. Retaining the option of chemical fumigation throughout such a transition could help to prevent disruptions to supply.

#### Scenario #2: Heat Treatment

Where possible, flour mill operators will choose to disinfest mills with heat treatment. Heat disinfestation of a flour mill or food processing facility entails heating the structure to approximately 55°C (130°F) over a 6-8 hour period of time, holding that temperature for 24 hours, and then allowing it to cool over a period of 12 hours. Large industrial heaters are used to heat the mills; fans and temporary ductwork are used to diffuse the heat evenly throughout the building. The heaters used may run on natural gas, propane, or electricity; the gas or propane heaters have lower operating costs than electric heaters and heat more evenly (Akdoğan et al., 2005; Beckett et al., 2007). Steam heat may also be used in a facility that is already equipped with a boiler system.

The analysis assumes that flour mill operators will conduct full heat disinfestations – the mill is shut down for three days and the entire structure is heated at once. In reality, mill operators may decide to conduct partial heat treatments. A full heat treatment, where the entire mill is shut down, is used as the comparison because it is most similar to a chemical fumigation scenario. However, the ability to do partial heat treatments, i.e., certain rooms, floors, or production lines with serious infestations, is an advantage of using heat treatments; partial chemical fumigations would be impractical because the entire mill would still need to be evacuated.

The costs of switching from sulfuryl fluoride fumigation to the heat treatment scenario will include the initial cost of investment and energy costs. With heat disinfestation, there are no additional days of downtime as there are in the Product Removal scenario. As mentioned earlier, a full chemical fumigation takes two to three days; a heat treatment can be conducted in the same amount of time. It takes approximately 6-8 hours to heat a facility to the target temperature of 50–57°C (122–135°F); the temperature should be held for at least 24 hours to make sure that the heat reaches insects hiding in remote areas of the building. Assuming a facility is normally around 26.7°C (80°F), it would take 5-6 hours at the standard heating rate of 5°C / hour (Beckett et al., 2007). Cooling can occur a bit faster – 5-10°C per hour. This gives a total heat disinfestation time of less than 48 hours, which is equal to or less than the amount of time needed for a chemical fumigation with sulfuryl fluoride.

It is always necessary to clean a flour mill before a heat disinfestation. The additional cleaning would not represent an increase in labor costs, however, since deep cleaning also precedes a chemical furnigation to ensure that it is efficacious. Flour and other food particles are not easily penetrated by chemical furnigants or heat, so it is important that a facility is clean before disinfestation begins (Fields & White, 2002).

## Cost Categories and Estimates

Initial equipment investment. It is possible to contract the services of a professional heating crew to conduct heat treatments. The cost for this service can run anywhere from \$0.02 to \$0.15 per cubic foot (Raj Hulasare, personal communication, November 2008). Depending on how much the equipment is used, this would be more expensive in the long run than purchasing the equipment (e.g., heaters, fans, etc.) to conduct the heat treatments. If sulfuryl fluoride was unavailable, many facilities would switch to heat on a permanent basis. Therefore, this analysis assumes that each flour mill will invest in its own heaters and equipment.

BEAD acquired information on the costs of purchasing equipment to heat a 500,000 cubic foot and 1,000,000 cubic foot mill from Raj Hulasare, senior scientist and product manager at Temp Air, Inc. The estimates also included the operating costs of gas and electricity to run the heaters which are included in the next section on energy costs.

The largest investment cost for conducting heat treatments is the large propane or gas-powered heaters. Heaters are purchased for a facility according to the BTUs needed for the size of the facility in cubic feet. Other factors which affect the BTUs needed to heat a facility are the overall surface area (e.g., walls, floors, etc.), construction materials (e.g., wood, concrete, brick, glass, etc.), the air tightness of the facility, and even the strength and direction of prevailing winds affect both the efficacy and the cost of heat treatments (Chayaprerst, 2006). The estimates are based on an average facility in terms of these other factors. If the mill in the budget were about 500,000 cubic feet, it could be heated with nine million BTUs, which could be delivered by two of Temp Air's largest model of heater, the THP-4500. If the mill in the budget were about one million cubic feet, it could be heated with four of the THP-4500 heaters. The heaters cost about \$33,750 each, so total costs would be \$67,500 for the 500,000 cubic foot mill and \$135,000 for the one million cubic foot mill.

In addition to the heaters, a facility will need to purchase fans and a wireless temperature monitoring system. The 500,000 cubic foot facility would need about 70 fans at \$550 each, and the one million cubic foot facility would need about twice that many. The temperature monitoring system runs approximately \$20,000 for the smaller facility and \$40,000 for the larger one. In some cases, modifications will need to be made to sprinkler systems to withstand higher temperatures. Estimates for such modifications were not available.

Total initial equipment investment costs are \$125,055 for the 500,000 cubic foot mill and \$249,090 for the one million cubic foot mill, \$12,506 and \$24,909 average annual costs over a ten year period, respectively.

Energy and Other Operating Costs. The energy requirements needed to heat a one million cubic foot facility to 50°C differ based on construction materials, number of partitions, and other factors. Natural gas is less expensive than propane although both are subject to price fluctuations. For example, natural gas prices have increased by nearly 100 percent over the past ten years and have fluctuated to even higher levels (U.S. EIA, 2010). The estimates used in the analysis were provided by Temp Air, and they represent the cost to power heaters with natural gas. For the smaller facility, the cost of natural gas and electricity to run the two THP-4500 heaters for 30 hours (six hours to heat up and 24 hours to hold the temperature) was approximately \$3,031. For the larger facility using four heaters, the cost of gas and electric was about \$6,062. Assuming three fumigations per year, the cost of energy (gas and electric to run the heaters) would be approximately \$9,093 for the 500,000 cubic foot facility and \$18,186 for the one million cubic foot facility.

In addition to the cost of energy, heavy duty temporary ductwork is needed to move the heat around the building. This ductwork can be used five to six times if properly cared for, so it is assumed that one purchase of ductwork lasts through six fumigations (about two years) before it must be replaced. The ductwork for the smaller facility costs about \$15,000 in total or \$2,500 per use; for the larger facility, the cost is about \$25,000 in total or \$4,167 per use. Over three fumigations, this adds up to \$7,500 per year for the smaller facility or \$12,500 for the larger facility.

Total energy and operating costs for three heat treatments a year add up to \$16,593 for the 500,000 cubic foot facility and \$30,687 for the one million cubic foot facility.

# Economic Impact of Switch to Heat Treatment Scenario

Table 5 shows the cost estimates for a transition from sulfuryl fluoride fumigations to heat treatments for a 500,000 cubic foot and a one million cubic foot facility. The 10-year baseline is the same as in the first scenario. For the 500,000 cubic foot facility, disinfestation costs with sulfuryl fluoride are eliminated and the fixed and operating costs of heat treatment are added in. For the 500,000 cubic foot facility, average annual net revenue increases by \$28,500 (0.8%) as a result of a decrease in disinfestation costs. For the one million cubic foot facility, average annual net revenues increase by \$2,000, a negligible percent increase over a ten year period. A significant increase in energy costs could change this scenario. However, even if energy costs doubled, the increase in costs would be approximately \$3,000 per year for the 500,000 cubic foot facility and \$6,000 per year for the one million cubic foot facility.

Table 5. Summary of flour mill income and expenses over ten years under Scenario #2: Heat Treatment; Estimates for a 500,000 cubic foot and a 1,000,000 cubic foot mill

|                        | 10 vm over             | 500,000 cubic foot facility |            | 1,000,000 cubic foot facility |            |
|------------------------|------------------------|-----------------------------|------------|-------------------------------|------------|
|                        | 10-yr avg:<br>Baseline | 10-yr avg:<br>Heat Trtmnt   | Change     | 10-yr avg:<br>Heat Trtmnt     | Change     |
| Total Shipped (cwt)    | 2,450,000              | 2,450,000                   |            | 2,450,000                     | , y        |
| Total Revenues/Sales   | \$ 31,835,700          | \$ 31,835,700               |            | \$ 31,835,700                 |            |
| Operating Costs        | \$ 28,281,000          | \$ 28,252,500               | -\$ 28,500 | \$ 28,279,000                 | -\$ 2,000  |
| Mfg and Sales Costs    | \$ 1,537,300           | \$ 1,508,800                | -\$ 28,500 | \$ 1,535,300                  | -\$ 2,000  |
| Disinfestation 1       | \$ 57,600              |                             | -\$ 57,600 |                               | -\$ 57,600 |
| Equipment <sup>2</sup> |                        | \$ 12,500                   | \$ 12,500  | \$ 24,900                     | \$ 24,900  |
| Energy & Other 3       |                        | \$ 16,600                   | \$ 16,600  | \$ 30,700                     | \$ 30,700  |
| Cost of Goods Sold     | \$ 26,743,700          | \$ 26,743,700               |            | \$ 26,743,700                 |            |
| Net Revenue            | \$ 3,554,700           | \$ 3,583,200                | \$ 28,500  | \$ 3,556,700                  | \$ 2,000   |

<sup>&</sup>lt;sup>1</sup> Fumigation with sulfuryl fluoride, three times @ \$19,211, costs \$57,633; rounded to \$57,600.

# Results based on one disinfestation per year

As mentioned previously, some facilities do not fumigate three times per year. If a 500,000 cubic foot facility normally underwent one chemical fumigation per year, instead of three, and wanted to replace that chemical fumigation with heat treatment, its annual net revenues would decrease by approximately \$1,200. The net revenues for a one million cubic foot facility under this scenario would decrease by nearly \$16,000 (0.5%) per year from an increase in operating costs.

# Expected Transition Time for Switch to Scenario #2

Conducting effective heat treatments is a learned skill that requires training and trial and error (Bh. Subramanyam, personal communication, May 2010). Every mill has slight variations in design that will affect how heat distributes throughout the facility. For heat treatment to be as effective as chemical fumigation for disinfestation, each team of heat treatment personnel will need to learn the best practices specific to their plant or plants. BEAD thinks that it could take several years to purchase equipment, train personnel, and become proficient at using heat treatment as the primary method for disinfestation. Retaining the option of chemical fumigation throughout such a transition could help to prevent any market disruptions.

<sup>&</sup>lt;sup>2</sup> Total initial equipment investment costs are \$125,055 for the 500,000 cubic foot mill and \$249,090 for the one million cubic foot mill, \$12,506 and \$24,909 average annual costs over a ten year period, respectively. These figures are rounded to \$12,500 and \$24,900.

<sup>&</sup>lt;sup>3</sup> For the smaller facility using two heaters, the cost of energy to run the heaters is approximately \$3,031 per fumigation, \$9,093 in total rounded to \$9,100. For the larger facility using four heaters, the cost of energy to run the heaters is approximately \$6,062, \$18,186 in total rounded to \$18,200. The ductwork for the smaller facility costs about \$15,000 in total or \$2,500 per use; for the larger facility, the cost is about \$25,000 in total or \$4,167 per use. Over three fumigations, this adds up to \$7,500 per year for the smaller facility or \$12,500 for the larger facility. In total the energy and other operating costs are \$16,600 for the 500,000 cubic foot facility and \$30,700 for the one million cubic foot facility.

## **CRITICAL ASSUMPTIONS**

This analysis makes some assumptions that are critical to the findings. First, the analysis assumes that there will be sufficient time for flour mills to transition to one of the alternatives. If mills were left without a fumigant as they transition to one of the alternative scenarios, they could produce contaminated, adulterated products that could be a human health risk and would have to be destroyed. This could result in a supply disruption and/or higher prices for end products. In the event that there is an immediate removal of tolerances, the impacts for flour mills would be greater than what has been described previously.

In addition, Scenario #1 (Product Removal) assumes: 1) that the registrant would apply to EPA for appropriate label changes and 2) that, based on the proposed label changes, EPA concludes that use of sulfuryl fluoride in this manner would not lead to residues in food. If either of these assumptions is wrong, the impacts for flour mills would be greater than what has been described previously.

#### CONCLUSIONS

BEAD predicts, if there is a stay in the food tolerances for sulfuryl fluoride, flour mills will switch to one of two alternatives. One alternative is to move all flour out of the mill to fumigate with sulfuryl fluoride; a second alternative is to use heat treatments to disinfest the mill. Mills constructed primarily from wood, which make up about 20-25 percent of the mills in the U.S. may not have the option of using heat treatment. These mills will likely choose the first option, to move all food products out of the mill prior to fumigation, a method requiring additional expense and days of downtime. This method could result in considerably lower net revenues for flour mill operators and could require several years to successfully transition. Newer mills, i.e., those constructed primarily from concrete, will most likely choose the second option and replace chemical fumigation with heat treatments; this method requires a higher initial investment cost but may cost even less than chemical fumigation in the long run. Successful transition to heat treatments could also take several years. Transition time, in both scenarios, is needed so that staff can learn the new method and become proficient at using it in place of current practice.

For this reason, if there is an immediate revocation of sulfuryl fluoride tolerances, there is a possibility that contaminated food could enter into the food chain and result in human illness. If contaminated product is identified before entering into the food chain, it would have to be destroyed to comply with FDA regulations. Either scenario could cause a disruption in the supply of flour and result in higher food prices for consumers.

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# Appendix A. Food and Drug Administration Links

"Title 21, Code of Federal Regulations, Part 110.110 allows the Food and Drug Administration (FDA) to establish maximum levels of natural or unavoidable defects in foods for human use that present no health hazard. These "Food Defect Action Levels" listed in this booklet are set on this premise--that they pose no inherent hazard to health." (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/S anitation/ucm056174.htm).

Food Storage Compliance 580.100:

http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm07461 3.htm.

Compliance Guidelines:

http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/MacroanalyticalProceduresManualMPM/ucm084382.htm